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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,996	12/31/2003	Peter Zoth		8238

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EXAMINER	
SYED, ATIA K	

ART UNIT	PAPER NUMBER
4185	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/748,996	ZOTH ET AL.	
	Examiner	Art Unit	
	ATIA SYED	4185	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *31 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-14 are rejected under 35 U.S.C 103(a) as being unpatentable over Givens et al. (US 6,916,291 B2) in view of Dolphin (US 5,916,174).

Regarding **claim 1**, Givens et al. discloses a method for audiological screening of infants and newborns employing a handheld screening device having acoustic transmitters (**fig 11, item 475; column 18, lines 59-63**), microphone collection means (**fig 11, item 481; column 18, lines 59-63**), a digital signal processor (**fig 11, item 450: local device which has a signal processor; column 18, lines 64-65**), signal transmitters, receivers (**fig 11, column 18, lines 34-42; local device can receive information and transmit responses**) and a display screen (**column 19, lines 60-67; column 20, lines 1-3; local device is coupled to computer or laptop or the like**) comprising:

a. generating one or more stimuli with the acoustic transmitters of the handheld screening device in each ear canal of an infant or newborn (**fig 11; column 18, lines 59-66**),

b. collecting any transient evoked and/or distortion product otoacoustic emission signals generated by the cochlea in each ear canal in response to the stimulus with the microphone collection means placed in the ear (**fig 11; column 18, lines 59-66**),

c. analyzing the response signals using binomial statistics, different artifact categories by the digital signal processor (**fig 11; column 18, lines 59-66; disclosed is a local device with signal processing capabilities**),

d. transmitting all results all patient related data and all measurement relevant data from the handheld screening device transmitter to a patient tracking and screening system installed on a remote computer server via transmission means, using an external or built-in modem like interface and a predefined protocol (**fig 11; column 18, lines 59-66; discloses a expert site, all the measurement relevant data is transmitted to expert site via the internet for evaluation by clinicians**) and

e. receiving and displaying on the handheld screening device display screen all patient related data directly from a patient tracking system installed on a main server via a link to the server (**fig 10; column 17, lines 36-67; column 18, lines 1-6**).

Givens et al. fails to disclose that the local audiological screening method incorporates scalp electrodes and/or it can collect any click or frequency stimulated brainstem response signals by placing electrodes on the scalp.

However, Dolphin discloses an infant audiological screening device which comprises electrodes (**figs 1 and 2**) and it can collect any click or frequency stimulated brainstem response (**column 5, lines 60-67; column 6, lines 3-6**).

3. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the teaching of Givens et al. in view of Dolphin since by considering more factors for the diagnostic procedure can improve the functionality and results of the procedure.

Regarding **claim 10**, Givens et al. discloses a device for audiological screening of infants and newborns comprising:

a. means for generating one or more stimuli with acoustic transmitters in each ear canal of an infant or newborn (**fig 11; column 18, lines 59-66**),

b. means for collecting any transient evoked and distortion product otoacoustic emissions generated by the cochlea in each ear canal in response to the stimulus with microphone means for generating a frequency mixed product electric signal (**fig 11; column 18, lines 59-66**),

c. means for analyzing the response signals using binomial statistics, different artifact categories by a digital signal processor associated with the signal collecting means (**fig 11; column 18, lines 59-66; disclosed is a local device with signal processing capabilities**),

d. means for transmitting the results all patient related data and all measurement relevant data directly from the screening device to a patent tracking system installed on a remote computer server(**fig 11; column 18, lines 59-66; discloses a expert site, all the measurement relevant data is transmitted to expert site via the internet for evaluation by clinicians**) and

e. means for receiving and displaying on the handheld screening device display all patient related data directly from a patient tracking system installed on a main server(**fig 10; column 17, lines 36-67; column 18, lines 1-6**).

Givens et al. fails to disclose that the local audiological device has scalp electrodes and/or it can collect any click or frequency stimulated brainstem response signals by placing electrodes on the scalp.

However, Dolphin discloses an infant audiological screening device which comprises electrodes (**figs 1 and 2**) and it can collect any click or frequency stimulated brainstem response (**column 5, lines 60-67; column 6, lines 3-6**).

4. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the teaching of Givens et al. in view of Dolphin since by considering more factors for the diagnostic procedure can improve the functionality and results of the device.

Regarding **claims 2 and 11**, Givens et al. discloses a method and device for audiological screening wherein the means to transmit the frequency mixed product electric signal from the

audiological screening device to a remote computer system comprises dial-up connections using a built-in or attached analog, digital or mobile-phone modem (**column 19, lines 48-60**).

Regarding **claim 3**, Givens et al. as modified by Dolphin discloses a method for audiological screening wherein the means to transmit the frequency mixed product electric signal from the audiological screening device to a remote computer system comprises LAN connections to transfer and receive data in email-, ftp-, and internet (**column 19, lines 60-65; column 22, lines 36-40**).

Regarding **claim 4 and 5**, Givens et al. as modified by Dolphin discloses a method for audiological screening including sending patient list data and other information from the audiological screening device to the remote computer server, wherein the patient information includes a list of patients that are to be tested next, along with information on the patients required by the screening program, and other related information including known risk factors or general comments (**column 17, lines 36-51**).

Regarding **claim 6**, Givens et al. discloses a method for audiological screening wherein the audiological screening device is programmable from the remote computer server (**column 19, lines 3-6**).

Regarding **claims 7 and 13**, Givens et al. discloses a method and device for audiological screening wherein the remote computer server receives and transmits screening and patient data

via the patient tracking and screening system, which also controls the handheld screening device procedures with respect to:

a. setting the real time clock of the screener user **(fig 11, item 490; column 19, lines 34-47)**,

b. providing program parameters **(column 19, lines 3-6)**,

c. uploading software upgrades to a device **(column 15, lines 54-58)**.

d. sending messages to the screener user, including service-issues and procedures **(column 10, lines 13-19)**.

Regarding **claims 8 and 14**, Givens et al. discloses a method and device wherein service-issues are dependent on measurement results **(column 9, lines 35-59)**.

Regarding **claims 9 and 12**, Givens et al. discloses a method and device including combining an audiological screening database with other newborn screening data, and using and accessing to a commonly used database on a computer or server which generates and then stores all patient and result data for different screening methods **(column 5, lines 33-43)**.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references are cited for disclosing related limitations of the applicant's claimed and disclosed invention.

Feezor; Michael D. (US 4038496 A), **Freeman; Michael J.** (US 4320256 A), **Eckstein; Leo K.** (US 4964304 A), **Lovett et al.** (US 4989251 A), **Sturner; Raymond A. et al.** (US 5303327 A),

Braun; Leroy et al. (US 5811681 A), **Iliff; Edwin C.** (US 6022315 A), **Knappe; Michael E. et al.** (US 6061431 A), **Joao; Raymond Anthony** (US 6283761 B1), **Hou; Zezhang** (US 6322521 B1), **Raviv, Gabriel** (US 20040204191 A1).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Atia Syed (Tel No. 571-270-7134).The examiner can normally be reached on Monday-Friday, 8:30AM to 3:30PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrell Mckinnon can be reached on 571-272-4797. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./ 12/24/2008

Examiner, Art Unit 4185

/Len Tran/

Supervisory Patent Examiner, Art Unit 3752